

3738



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Christopher T. Boyle Atty. Docket No.: 6006-018  
Serial No.: 09/716,146 Group Art Unit: 3738  
Filed: November 17, 2000 Examiner: Cheryl L. Miller  
For: DEVICE FOR *IN VIVO* DELIVERY OF BIOACTIVE AGENTS AND METHOD OF  
MANUFACTURE THEREOF

Commissioner of Patents and Trademarks  
Washington, D.C. 20231

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INFORMATION DISCLOSURE STATEMENT

(first page for use during pendency of application)

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Identification of Time of Filing
3. ☐ Request for consideration of Information Disclosure Statement Submitted After Allowance
4. ☒ Statements With Respect To Listing of Information
5. ☐ Statements With Respect To Translations of Non-English Information
6. ☒ Statements With Respect To Copies of Listed Information Items Accompanying This Statement
7. ☐ Statement of Non-Possession of Documents
8. ☐ Concise Explanation of Listed Information Items

This statement concludes with section 9, PTO-1449 and section 10, Identification of Person(s) Making This Information Disclosure Statement.

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this Information Disclosure Statement (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Date: December 6, 2002

Jackie Arnold

(Type or print name of person mailing paper)

(Signature of person mailing paper)

## 1. Preliminary statements

Applicants submit herewith patents, publications or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR 1.56.

While this Information Disclosure Statement may be "material" pursuant to 37 CFR 1.56 it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(b) the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

**NOTE:** *THE FOLLOWING REQUIREMENTS MUST BE MET TO ASSURE THAT ALL ITEMS LISTED ON THE INFORMATION STATEMENT ARE CONSIDERED: If the Information Disclosure Statement is submitted before the claims have been indicated as allowable and includes (1) a listing of patents, publications or other information, (2) a concise explanation of the relevance of each listed item and (3) a copy of each listed item or the relevant portion of the listed patents, publications or other information (along with a translation of pertinent portions of foreign language items, if available) then it must be considered by the Examiner. The Examiner may consider a citation for any reason, whether or not the citation is in full conformance with this procedure. MPEP ' 609.*

*(Text continued on page 6-13)*

2. Identification Of Time Of Filing

This Information Disclosure Statement

(check and complete (a), (b), (c), (d), or (e))

(a) ☐ accompanies the new patent application submitted herewith. 37 CFR 1.97 (a)

NOTE: If this item is checked then use FRONT PAGE with Express Mail Certificate of Mailing corresponding to type of mailing for a new case.

(b) ☐ is filed within three months after the filing date of the application or prior to the mailing date of the first Office action, whichever is later. 37 CFR 1.97(b)

(c) ☒ is being filed after the time period specified in §1.97(b), but before mailing of a final action under §1.113, a Notice of Allowance under §1.311, or and action that otherwise closes in the application (37 C.F.R. §1.97(c)) and is accompanied by:

☐ Statement under 37 CFR §1.97(e); or  
☒ Fee under 37 CFR §1.17(p);

(d) ☐ is being filed after the time period specified in §1.97(c), but before payment of the issue fee (37 C.F.R. §1.97(d)) and is accompanied by:

☐ Statement under 37 CFR §1.97(e); or  
☐ Fee under 37 CFR §1.17(p);

(e) ☐ is a supplemental Information Disclosure Statement under 37 CFR 1.99

☐ a previous Information Disclosure Statement was filed on

NOTE: Updating of the Information Disclosure Statement should be submitted to the PTO with reasonable promptness and shall be accompanied by explanations of relevance and by copies of art in accordance with the requirements of the Information Disclosure Statement itself. 37 CFR 1.99 The transmittal should include a statement explaining why the Information was not earlier transmitted (and this can be done in the space below). If the transmittal is after allowance it shall include such an explanation (this is provided for in Request for Consideration of Information Disclosure Statement Submitted After Allowance). MPEP' 609.

☐ this supplemental Information Disclosure Statement is being submitted as the information was brought to attention

(f) ☐ The art was encountered in the course of the prosecution of the corresponding foreign application(s) in

(name(s) of country(ies) and serial number(s))

#### 4. Statements With Respect To Listing Of Information

A list of the patent(s) and/or publications is set forth on the attached (Section 9) Four page(s) of Form PTO-1449 (Modified).

**NOTE:** In completing PTO-1449 (Modified) it should be kept in mind that 37 CFR 1.98(a) requires that "All United States patents listed should be identified by their patent numbers, patent dates, and names of the patentees. Each foreign published application of patent should be cited by identifying the country or office which issued it, the document number and publication date indicated on the document. Each printed publication should be identified by author (if any), title of the publication, pages, date and place of publication."

The Notice of August 5, 1985 (1057 O.G. 41) States: "Among the information that should be provided on Form PTO-1449 is the date of the citation. In addition, it is helpful if the class and subclass of each citation is provided. It is appreciated that classification information may not be known at the time Form PTO-1449 is prepared. When classification information is not known, draw a line in the boxes under the class and subclass heading adjacent to the citation for which classification information is not known."

**NOTE:** "The reference designations "AA", "AB", etc. (referring to Applicants' reference A, Applicants' reference B, etc.) will be used by the Examiner in the same manner as the Examiner's reference designations "A", "B", "C", etc. on Office Action Form PTO-1142." Notice of August 15, 1980 (998 O.G. 5).

**NOTE:** REPRESENTATIVE ITEMS: "When two or more patents or publications considered material are substantially identical, a copy of the representative one may be included in the statement and others merely listed." 37 CFR 1.98(b).

**WARNING:** The Notice of December 23, 1982 (1027 TMOG 7-62) points out. "The final rule states clearly that the publication date indicated on the document should be submitted. This will not serve to preclude a showing of a different, actual publication date. Another purpose of the citation requirement in this section is to permit ready reference to the document from its citation."

The Notice of August 5, 1985 (1057 O.G. 41) states: "Note that the listing citations of Form PTO-1449 does not raise an irrebuttable presumption that the citation is prior art. A holding by an Examiner that any citation of Form PTO-1449 is prior art to claimed subject matter can be rebutted by procedures commonly used to rebut the prior art status of the Examiner's citations on Form PTO-892, "Notice of References Cited"."

(complete (a) or (b) if applicable)

(a) ☐ \_\_\_\_\_ is believed to be representative of the following patents or publications:

(b) ☐ \_\_\_\_\_ in the English language is believed to be the equivalent of the following non-English patents or publications:

## 5. Statements With Respect To Translations of Non-English Information

*NOTE: "A translation of the pertinent portions of foreign language patents or publications considered material should be transmitted if an existing translation is readily available to the applicant." 37 CFR 1.96(b).*

- ☐ Submitted herewith is an English translation of the following foreign language patents, publications or information or of those portions of those patents, publications or information considered to be material:

- ☐ No English language translations of the foreign language patents, publications or information or parts thereof are readily available, except for those listed above.

## 6. Statements With Respect To Copies of Listed Information Items Accompanying This Statement

*NOTE: 37 CFR 1.98(a) requires that the Information Disclosure Statement shall be accompanied by a copy of each listed patent or publication or other item of information in written form or of at least the portions thereof considered by the person filing the disclosure statement to be pertinent.*

*37 CFR 1.56(b) states: "Disclosures .... must be accompanied by a copy of each foreign patent document, non-patent publication, or other non-patent item of information in written form which is being disclosed or by a statement that the copy is not in the possession of the person making the disclosure ..."*

*"The portion of a document required to be submitted under ' 1.56(b) is the portion which is material to the examination of the application under ' 1.56(a).  
"Notice of November 30, 1983, 49 FR 5-48, January 4, 1984.*

*There is no assurance that art or other information not submitted with copies of listed items in accordance with the guidelines will be considered by the Examiner. MPEP' 609.*

A copy of

☒ each

☐ none

☐ only those listed below

of the items on PTO-1449 (Modified) is supplied herewith:

*(indicate if only a portion of a listed item is being supplied)*

*NOTE: If each listed item is not supplied herewith, complete Section 7, Statement of Non-Possession of Documents, to ensure that Information Disclosure is considered and/or to avoid an Office Action.*

## 8. Concise Explanation of Listed Information Items

**NOTE:** 37 CFR 1.98(a) requires that the Information Disclosure Statement **shall** include a "concise explanation" of the relevance of each listed item.

*This "concise explanation" may be nothing more than identification of the particular figure or paragraph of the patent or publication which has some relation to the claimed invention. It might be a simple statement pointing to similarities between the listed item and the claimed invention. It is permissible but not necessary to discuss differences between the listed item and the claims. It is thought that the explanation of relevance will be useful to the Examiner and should not be significantly burdensome for the applicant to prepare. A statement to the effect that an item is listed because it was cited during the prosecution of a counterpart foreign application and is not considered material to the examination of the U.S. application, is to be considered as satisfying the concise explanation requirement of 37 CFR 1.98(a). MPEP ' 609.*

*There is no assurance that art of other information not submitted with a concise explanation of listed items in accordance with the guidelines will be considered by the Examiner. MPEP ' 609.*

A concise explanation of the items listed on PTO-1449 (Modified) is:

☒ not given

☐ given for only some listed item(s)

☐ given for each listed item

PTO-1449 (Modified)  
REFERENCE DESIGNATION

CONCISE EXPLANATION



Identification Of Person(s) Making This INFORMATION DISCLOSURE STATEMENT

NOTE: 37 CFR 1.56(b) states: "Disclosures . . . may be made to the Office through an attorney or agent having responsibility for the preparation or prosecution of the application or through an inventor who is acting in his or her own behalf."

The person making this statement is

(check each applicable item (a) and (b))

(a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

Type name of inventor who is signing

(b) ☒ the attorney who signs below on the basis of:

(check each applicable item)

☐ the information supplied by the inventor(s)

☐ which has been reviewed by the attorney

☐ which has **not** been reviewed by the attorney

☒ the information in the attorney's file

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SIGNATURE OF ATTORNEY

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